

Preparation for a Grant Application

Which form do I use to apply for an NIH research grant?

For most grant types, such as the R01 (<http://grants.nih.gov/grants/guide/pa-files/pa-10-067.html>), use the electronic forms in the Grant Application Package.

With few exceptions, all types of grant applications are electronic. When determining which form, please be sure to read the funding opportunity announcement.

When is my application due?

Go to the [Standard Due Dates for Competing Applications](#) for all NIH receipt dates. Also, please read the funding opportunity announcement (FOA) carefully regarding application due dates. For example, the FOA for NINR's T32 states that applications are received annually only on the May 25th submission date. RFAs typically have their own special receipt dates, which will be the definitive receipt date for those FOAs.

What does the Center for Scientific Review (CSR) do with my application after receiving it?

CSR assigns your application to an integrated review group for initial peer review and an NIH Institute or Center for funding. For a list of Scientific Review Panels, visit URL: <http://era.nih.gov/roster/>

For more information, read CSR's [The Peer Review Process](#).

What's the difference between a request for applications (RFA) and a program announcement (PA)?

NIH publishes two types of funding opportunities to stimulate submission of applications in areas of high priority or special interest. Each Funding Opportunity Announcement (FOA) includes information about the funding mechanism supported and the appropriate forms to use when applying. NIH publishes announcements with additional information and instructions for each FOA in the NIH Guide.

Requests for applications (RFAs) invite grant proposals in well-defined areas of research to accomplish a scientific program purpose at a specified funding level. RFAs have a one-time receipt date. They may be sponsored individually by one NIH Institute or Center or, frequently, by several Institutes and Centers that share a particular research interest. Applications submitted in response to RFAs are reviewed by specially convened study section review groups and compete with each other for the specified set-aside of funds.

Program announcements (PAs) describe new, continuing, or expanded program interests of the NIH Institutes and Centers or announce the availability of a new mechanism of support and approximate level of funding. They usually remain in effect for a minimum of three years, at which time they are either inactivated or renewed. Applications submitted in response to PAs compete for funding through the regular scientific peer review process. Applicants should NOT insert PA numbers or titles that are no longer active in their application. The PA expiration date is listed on the first page of each FOA.

Most of the research funded by NINR results from investigator-initiated application proposals. Investigators are encouraged to contact the appropriate NINR Program Director regarding their research ideas. [Click here](#) for a list of areas of research supported by NINR. In general, NIH and NINR are focusing on program announcements and investigator-initiated research, and fewer RFAs are being issued.

What are NINR's research priorities?

The primary areas of research funded by NINR are health promotion/disease prevention, eliminating health disparities, caregiving, symptom management, and self-management, and quality of life. NINR is the lead Institute at NIH on research on care at the end of life—an important emerging field. The NINR Mission and Strategic Plan help to direct funding decisions. Expert panels and research working groups help NINR to identify gaps in current knowledge that require research. In addition, NINR considers guidance from the National Advisory Council for Nursing Research and from Congressional mandates, as well as workshops or conferences convened to inform a science area.

Applicants should discuss their research ideas with a Program Director who has expertise in their particular area of science interest. Funding decisions for any application are related to its scientific merit, its relevance to program priorities, and the availability of funds.

What research grants are currently funded by NINR?

Research grants and traineeships that are currently funded by NINR and by other NIH components may be found in RePORTER. You may search by several criteria including science topic, principal investigator, institute (such as NINR), type of grant, fiscal year(s) and so on.

Is it possible to obtain a copy of an application submitted by another investigator?

The Freedom of Information Act ("FOIA"), 5 U.S.C. 552, provides individuals with a right to access

records in the possession of the federal government. These rights are subject to certain exceptions described on the NIH [FOIA site](#). Read carefully the requirements for submitting a request and follow the instructions for the information requested in order to facilitate your request. You may also consider asking the principal investigator directly for a copy of the application of interest. Submitted, but unfunded applications, are not available through a FOI request.

The FOIA Office website contains additional information regarding FOIA (<http://www.nih.gov/icd/od/foia/index.htm>)

How can I find out whether NINR is interested in the kind of research I'm proposing?

Program staff of NIH's various institutes and centers are always available to speak with investigators, and, in fact, such contacts are encouraged during the preparation of an application. In addition to information about the application process and strategies to consider in preparing an application, program staff can provide feedback on the relative "fit" between the proposed research and the program interests of the Institute or Center.

NINR welcomes innovative proposals for clinical and basic studies across a broad continuum of health-related issues. The NINR current mission statement and Strategic Plan can be viewed [here](#). NINR's ongoing science areas of interest may be viewed [here](#). See also specific areas of research opportunity for the current fiscal year and current [program announcements and requests for applications](#). As a potential applicant for an NINR grant, you are strongly urged to contact one of the Program Directors in NINR's Office of Extramural Programs at (301) 594-6906 to discuss your research ideas with the [Program Director](#) in your area of interest. You may also email a one to two-page concept paper to the Program Director in your area of interest.

If you are unsure about the appropriate contact, send your concept to Dr. Yvonne Bryan, Chief, Office of Extramural Programs, who will forward it to the appropriate NINR Program Director or to another NIH Institute or Center where the proposed research ideas would best fit. Dr. Bryan's email address is bryany@mail.nih.gov.

How do I know which mechanism to use in response to a specific Funding Opportunity Announcement (FOA) or for investigator-initiated applications?

There are several strategies to use in deciding which research or training mechanism to use. First, here are some useful definitions and background information. The *mechanism*, or *activity code*, designates a particular type of grant. For example, the R03 mechanism is a small grant for two years

of pilot work that is not renewable (there may be Institute or Center specific requirements for the mechanisms so FOA is always the best source). The R01 mechanism is the standard NIH grant for larger research projects that are based on pilot studies that yielded significant and published results. In addition to these two mechanisms, others include the R15, R21, F31, F32, K01, K23, R43 (small business), and so on. Note that there are many funding mechanisms at NIH but each Institute supports its own subset of mechanisms. See the [IC \(Institute or Center\) website](#) for specific mechanisms supported. In addition, the NIH Common Fund supports a series of cross-cutting, trans-NIH research programs.

Here are strategies to use in deciding the appropriate mechanism for an application.

1. Consult with an experienced investigator at your institution.
2. Review the FOA ([RFA](#) or [PA](#)) for the mechanism requirements if you intend to respond to a particular FOA.
3. Review the [funding opportunities](#) for the mechanisms of interest.
4. Discuss the mechanism options with a [Program Director](#) at NINR. Send your biosketch and a concept paper about your research project by email prior to your discussion to the program contact whose science area most closely matches your science interests. Do **NOT** send the same materials to more than one program contact as your first contact will forward your material to the correct person if you err in your selection. It helps to be prepared to describe your personal research or training goals and the aims, population, and methods for the research problem of interest.

When should I talk with or email my NIH Institute program official?

NINR Program Directors serve as a point of contact and a resource for research and research training applicants. They also monitor research progress through annual reports and through other communications with investigators. Program Directors are appropriate points of contact for individuals during application preparation, after the review process, during resubmissions if necessary, and throughout the duration of a grant. During the application phase the Program Directors may assist with identifying the science area fit with NINR's mission and assist in deciding what the appropriate funding mechanism is. After review, the Program Director should be contacted with any questions or to discuss the summary statement resulting from the review. During a grant funding period, the investigator should appraise the Program Director of any problems in conducting the research or any untoward events. In addition, the investigator may wish to discuss the application for the next phase of research with the Program Director.

How do I know if I am a *new investigator* by NIH criteria?

A **New Investigator** is an NIH research grant applicant who has not yet been awarded a substantial, competing NIH research grant. For example, a Program Director/ Principal Investigator (PD/PI) who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a small grant (R03) or

an Exploratory, Developmental Research Grant Award (R21) retains his or her status as a New Investigator. For a complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator, visit http://grants.nih.gov/grants/new_investigators/resources.htm.

How does NIH describe an Early Stage Investigator (ESI)?

An **ESI**, or **Early Stage Investigator**, is a New Investigator who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet been awarded a substantial, competing NIH research grant. The dates that start the period of classification as an Early Stage investigator are entered in the investigators eRA Commons Profile (<https://commons.era.nih.gov/commons/>).

Why does NIH allow multiple Principal Investigators on individual research awards?

This effort represents an NIH Roadmap initiative (see <http://nihroadmap.nih.gov/interdisciplinary/>) as well as a response to a Federal-wide directive to formally allow more than one Principal Investigator (PI) on individual research awards. The policy offers new approaches to maximize the potential of “team science” efforts. The multiple PI model supplements, and does not replace, the traditional single Principal Investigator (PI) model. Although the single-PI model clearly continues to work well and encourages creativity and productivity, it does not always encourage multidisciplinary efforts and collaboration. Increasingly, health-related research involves teams that vary in terms of size, hierarchy, location of participants, goals, disciplines, and structure. The selection of the multiple-PI versus single-PI option is the decision of the applicant institution and investigators, and must be based on the needs of the research proposed. Although the number of applications submitted using the multiple-PI model is relatively small compared with those within the traditional single-PI format, the impact of the research supported through multidisciplinary efforts can be significant.

How do I know how much budget I can request?

Budget requests must be science driven. The only grant mechanism supported by NINR for which there is no stated limit is the R01. Although there is no stated limit on funding levels for these grants, R01 applications assigned to NINR that request \$350,000 or more in direct costs are brought to NINR's National Advisory Council for special consideration of their requested budget before they can be funded. Because of the proposed large investment of NINR's resources in these applications, the Council is asked to consider the relevancy of the research to the Institute's mission and to determine whether, from a policy perspective, the expenditure is warranted in relation to the research to be accomplished. **In addition, any application requesting \$500,000 or more in direct costs for any year must have NINR (or other Institute) approval before the application can**

be submitted and will not be accepted without prior approval. The request must be submitted to the Program Director at least six weeks before the submission date.

Applications: See the NIH Grants Policy Statement for details about this requirement. (http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_2003.pdf)

Where can I get help with grantsmanship?

Investigators at your institution who have received NIH funding can serve as sources of information and consultation regarding grant preparation. In addition, the offices of sponsored research at many institutions offer assistance and/or workshops on the preparation of NIH grant applications. Finally, NIH sponsors Regional Seminars on Program Funding and Grants Administration (for upcoming seminars <http://grants.nih.gov/grants/seminars.htm>). Applicants are encouraged to take advantage of such services before they begin to develop their research proposals. Review carefully the application instructions and the links within the instructions for application process details. There are a number of **grant writing resources** on the NIH website. Several institute tutorials, tip sheets, and review resources are available [here](#).

What funding opportunities are available for applicants from foreign countries?

Non-USA citizens and organizations may apply for NIH grants. There are some limitations on types and amounts of grants. Foreign investigators would, for example, need to indicate how the proposed research would be relevant to the public health of the people of the U.S.A. A Kirschstein-NRSA individual fellowship award is made only to a U.S. citizen or a non-citizen national. More information about “foreign grants” can be found at http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm. Scroll to the header: *Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components*.

Are there special requirements if my project includes Genome Wide Association Studies (GWAS)?

Yes, All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission of data is not possible. Also see the document entitled “[NIH Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications Under NIH’s Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies \(GWAS\)](#)”, which

contains useful information on the institutional certification process as well as other requirements for institutions performing NIH-funded genome-wide association studies (http://grants.nih.gov/grants/gwas/gwas_ptc.pdf).

What is a Certificate of Confidentiality and will I need one for our study?

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants. For more information, see link below.

<http://grants.nih.gov/grants/policy/coc/>

Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. Thus, NIH would like to encourage their appropriate use. NIH is making information widely available to investigators working on sensitive biomedical, behavioral, clinical or other types of research at this Certificate Kiosk. Information may get added to this site periodically. Readers are encouraged to check back periodically.

What do I do If I have a question about Financial Conflict of Interest (FCOI)?

The NIH is committed to preserving the public's trust that the research supported by us is conducted without bias and with the highest scientific and ethical standards. We believe that strengthening the existing regulations on managing financial conflicts of interest is key to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector.

The latest information about FCOI may be obtained from the NIH website at:

<http://grants.nih.gov/grants/policy/coi/>

Training Opportunities

If I have nearly completed or recently completed my doctorate, what are the next steps in the research career path?

There is no one "right way" to build a research career since individuals follow different paths to their doctorates and need to consider different priorities and explore different opportunities in planning their futures. While each individual must determine their own best research training and grants path, a full progression to a research program, for a beginner, could include the following sequence: predoctoral traineeship (F31 or T32)--> postdoctoral traineeship (F32 or T32)--> career development (K Series) award --> research (R Series) awards.

For all new doctoral program graduates, the first step is to publish dissertation findings in a peer reviewed journal. Disseminating the findings demonstrates a commitment to the full research process. Research training beyond the doctorate is strongly recommended. NIH offers a number of research training and career development options that provide a continuum of opportunities for beginning investigators. The characteristics of these mechanisms are described below. If you have questions about your eligibility or about which training mechanism may be best for you, contact Dr. David Banks.

Postdoctoral Training Mechanisms

What is the difference between an individual fellowship and an institutional research training grant?

An **individual fellowship** is awarded to an institution to support an individual predoctoral (F31) or postdoctoral (F32) student. The student applicant completes and submits an application to NIH, including a cover letter requesting assignment to NINR. The applicant should work with her/his research mentor in preparing the application to ensure that the mentor has approved the project and their role on the traineeship. An **institutional research training grant** (T32) enables schools of nursing with research programs to provide full-time predoctoral and/or postdoctoral research training. The institution with the training program grant selects the trainees to be appointed. See the T32 or training web page (<http://www.ninr.nih.gov/ResearchAndFunding/FundedNinrGrantsCollaborativeActivities/InstitutionalFile.htm>) within the institution website for contact or application information. Applications for a predoctoral or postdoctoral research training position on a T32 are not sent to NIH but rather to the specific institution which holds the T32 grant.

Institutional Training Awards (T32s) These grants are awarded to eligible institutions in support of predoctoral and postdoctoral research training to prepare scientists for careers in behavioral and biomedical research. Graduate students and postdoctoral trainees are appointed to positions on training grants by the training institutions. Individuals appointed to postdoctoral positions are expected to engage in at least two years of research or research training beginning at the time of appointment. Check the NINR website for a list of institutions with NINR-funded T32s. If you have questions about NINR's T-32 Institutional Training Programs, please contact Dr. Lois Tully.

For institutional training grants, are there specific instructions if my requested budget is \$500,000 or more in direct costs in any year?

Yes. Applicants requesting \$500,000 or more in direct costs for any year must carry out the following steps: 1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study; 2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and, 3) Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application. Please note that it is not sufficient to make a request to NINR to submit a budget of \$500,000 or more (direct costs) in any year. If you do not have a written agreement from NINR accepting your application, your application will be denied.

Must I still make a specific request if my T32 application includes \$500,000 (direct costs) in any year, given that the formula that will be applied by NINR to the requested tuition and fees will bring the final awarded budget below \$500,000 in each year?

Yes. Applicants should request full needs for tuition and fees. NINR will then apply the appropriate formula by offsetting the combined costs of requested tuition and fees at the rate in place at the time of the award ([see the Funding Announcement under which you are applying for additional information on the formula used](#)). **It is important to note that regardless of the final awarded budget, if you do not follow the instructions for requesting \$500,000 or more (direct costs in any year) at the time of application, your application will be denied.**

The following **individual** support mechanisms funded by NINR should be considered by post-doctorates:

Individual Postdoctoral Fellowships (F32). These fellowships are awarded by NIH to qualified applicants, selected as a result of a national competition, to support full-time research training related to the missions of its constituent institutes and centers. Before submitting an application for this type of award, it is incumbent upon the applicant to arrange for appointment to an appropriate institution and acceptance by a sponsor who will supervise the training and research experience. The institution may be a private (profit or not-for-profit) or public institution, including a Federal laboratory. The candidate's sponsor should be an active investigator in the area of the proposed research activity who will personally supervise the candidate's research. The sponsor must document, in the application, the research training plan and the availability of staff, research support, and facilities to provide a suitable environment for performing high-quality research training. Applicants proposing training at their doctorate institution or at an institution where they have been training for more than a year must thoroughly document the opportunity for new training experiences that would broaden their scientific background.

The ***NIH Pathway to Independence Award (K99/R00)*** is a new opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. Award recipients will be expected to compete successfully for independent R01 support from the NIH during the career transition award period. This Award will provide up to five years of support consisting of two phases. The initial phase will provide 1-2 years of mentored support for highly promising, postdoctoral research scientists. This phase will be followed by up to 3 years of independent support contingent on securing an independent research position. Award recipients will be expected to compete successfully for independent R01 support from the NIH during the career transition award period. The award is limited to postdoctoral trainees who propose research relevant to the mission of one or more of the participating NIH Institutes and Centers, for example, NINR.

Mentored Research Scientist Development Awards--Nursing (K01). These awards provide sponsored research experience for individuals to gain expertise in new research areas or in areas that would demonstrably enhance their scientific careers. Following this experience, candidates are expected to be able to pursue independent research careers. Candidates who have interrupted their careers because of illness or pressing family care commitments may apply if they can demonstrate their potential for productive independent research and the need for a mentored experience in order to achieve an effective reentry into research. Faculty members at institutions with a substantial

minority enrollment who wish to enhance their research skills through supervised research experiences at other research centers may also apply if they agree to return to their parent institutions after completion of the award. Career development awards are made for three years by NINR and are nonrenewable.

Candidates must have research or health-professional doctorates or their equivalents and must have demonstrated the capacity or potential for highly productive independent research in the period after the doctorate. Candidates must identify mentors with extensive research and must spend a minimum of 75 percent of full-time professional effort conducting research and research career development activities for the period of the award. The remaining 25 percent time should be devoted to other research-related and/or teaching or clinical pursuits consistent with the objectives of the award.

NIH Career Transition Award--Nursing (K22). This mechanism provides a period of support to provide research training experience in the NIH clinical research laboratories and to facilitate successful transition to an extramural environment as an independent researcher. The NINR Career Transition Award consists of an Intramural Support Phase and an Extramural Support Phase. The total period of combined intramural (on the NIH campus) and extramural (off campus) support is up to five years. Initially, up to three years of the research training program will be provided in the Intramural Support Phase in which the salary of the awardee will be commensurate with his/her level of experience. The final two years of the program, the Extramural Support Phase, will provide salary and funds for supplies, equipment and technical support thorough the NIH Career Transition Award.

Mentored Patient-Oriented Research Career Development Awards (K23). You may want to consider this mechanism if you are planning a career in patient-oriented research. It provides support for a period of supervised study and research for clinically trained professionals who have the potential to develop into productive clinical investigators in an area of patient-oriented research. While the development program focuses primarily on the conduct of patient-oriented research, there can be complementary appropriate laboratory research directly related to the patient-oriented research proposed in the application.

After the training phase, investigators will need to advance their program of research by applying for a research grant. Depending on the stage of the research conducted and published during training, the investigator may be ready for either a small research grant (R03, R15, R21) or a regular R01 research grant.

Research Grants

Academic Research Enhancement Awards (R15). These awards are intended to support health-related research projects conducted by faculty in institutions that are not research intensive. They enable qualified scientists to receive support for small-scale research projects. They create a research opportunity for scientists and institutions otherwise unlikely to participate extensively in NIH programs to participate in the Nation's biomedical and behavioral research effort. A list of ineligible institutions is published each fiscal year on the NIH website. If the name of a school does not appear on the list, it may be eligible to apply for AREA grants. [Click here](#) for more detailed information about the AREA program and a link to the list of [ineligible schools](#) for the current fiscal year.

The AREA program is a research grant program and not a training or fellowship program. Active involvement of undergraduate and graduate students in the proposed research is encouraged, and reviewers will consider whether the proposed project will expose undergraduate (preferably, if available) and graduate students to meritorious research. However, the application should not focus on training objectives and training plans should not be provided.

At institutions that have not been major recipients of NIH support, AREA grants may support small-scale, new or renewal, meritorious projects in biomedical and behavioral research, including:

- pilot research projects and feasibility studies
- development, testing, and refinement of research techniques
- secondary analysis of available data sets
- similar discrete research projects that demonstrate research capability

For Project Directors/Principal investigators (PD/PIs) who receive AREA funding, there are additional opportunities for administrative supplements to improve the diversity of the research workforce by supporting and recruiting high school and undergraduate students from groups that have been shown to be underrepresented (see PA-05-015). Dr. Paul A. Cotton is the NINR AREA contact and he may be reached at cottonp@mail.nih.gov.

Research Project Grants (R01s). The Research Project Grant (R01) is an award to support a discrete, specified, circumscribed project to be performed by named Project Directors/Principal Investigators (PDs/PIs) in areas representing the investigators' specific interests and

competencies, based on the mission of the NIH. The R01 is the original and historically the oldest grant mechanism used by the NIH to support health-related research and development.

The NIH awards R01 grants to institutions/organizations of all types. This ‘parent R01 mechanism (as opposed to one from a PA or RFA) allows the PDs/PIs to define the scientific focus or objective of the research based on particular areas of interest and competence. Although the PDs/PIs write the grant application and are responsible for conducting and supervising the research, the actual applicant is the research institution/organization.

Does NIH offer any special opportunities for underrepresented or disadvantaged groups, including minorities?

NINR has consistently offered opportunities to promote diversity in the biomedical, behavioral, clinical and social sciences research workforce, specifically in nursing science researchers. Over the years, NIH has developed a number of opportunities for underrepresented or disadvantaged groups, including minorities.

The Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowships to Promote Diversity in Health-Related Research (F31 Diversity) is one approach to increasing diversity of nurse investigators by providing doctoral students research career development opportunities with financial support. It is designed to improve the diversity of the health-related research workforce by supporting the training of doctoral students from groups that have been shown to be underrepresented among the scientific workforce. Such candidates include individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds.

The NINR ***Mentored Research Scientist Development Award for Underrepresented or Disadvantaged Investigators*** (K01) seeks to address the lack of diversity of qualified nurse scientists in research settings by enhancing the research capabilities of underrepresented or disadvantaged nurse investigators so that these individuals may establish research laboratories and research programs in nursing science. There is abundant evidence that the research, biomedical, and health enterprise will directly benefit from this broader inclusion.

Another resource for underrepresented individuals, ranging from high school to postdoctoral faculty, is the **Research Supplement to Promote Diversity in Health Related Research**. Special supplements to currently funded research grants are available to recruit and support underrepresented or disadvantaged students and investigators. The aim of these supplements is to

attract and encourage individuals to enter and pursue biomedical and behavioral research careers in areas within the mission of NINR. A request for a supplement may be submitted by the principal investigator at any time during their grant but there should be at least two years remaining on the grant at the time of the supplement award. Research supplements to promote diversity must support work within the scope of the original project. You may obtain more details about this mechanism from the program announcement (<http://grants.nih.gov/grants/guide/pa-files/PA-08-190.html>). Contact your NINR Program Director to discuss this award.

[Click here](#) for a complete list of research training and career development opportunities sponsored by NIH, including those designed to meet the special needs of underrepresented groups.

Is part-time effort allowed for pre- or postdoctoral National Research Service Award (NRSA) fellowships?

NINR does not support either short-term or part-time pre- or postdoctoral fellowships. You must make a fulltime commitment of 40 hours and must be compensated with a stipend. In addition, a NRSA may not be held concurrently with another Federally-sponsored fellowship or similar Federal award which provides a stipend or otherwise duplicates provisions of the NRSA. Please contact NINR staff if you have any questions about your eligibility for an award.

Human Subjects Research

What steps do I have to complete prior to using human subjects in my research?

The U.S. Department of Health and Human Services Office of Human Research Protections (OHRP) has developed two educational videos that provide information regarding the Department of Health and Human Services (HHS) regulations for the protection of human subjects of research described at 45 CFR part 46. One video discusses research use of human biological specimens and other private information; it can be accessed at: http://videocast.nih.gov/ram/ohrp_kaneshiro.ram. The second video discusses reviewing and reporting unanticipated problems and adverse events; it can be accessed at: http://videocast.nih.gov/ram/ohrp_carome.ram

Each video is approximately 20-25 minutes in length. An institution may reproduce or share these materials for educational purposes and may wish to consider incorporating the materials in their training programs. Additional OHRP information is available at: <http://www.hhs.gov/ohrp/>

General information about the inclusion of human subjects in NIH-supported research protocols is provided in the grant application instructions, along with requirements for detailed documentation regarding descriptions of (1) the proposed involvement of human subjects in the study, (2) the sources of research material obtained from individually identifiable human subjects, (3) plans for

subject recruitment and consent procedures, (4) potential risks, (5) procedures for protecting against or minimizing risks, and (6) how benefits outweigh risks. You also need to provide scientific justifications for inclusion or exclusion of populations (gender, minorities, and children). All three populations must be addressed and a plan for recruitment and retention must be included. The following resources provide details about preparing the human subjects component of the research plan:

Regulations, Policies & Guidance: http://grants.nih.gov/grants/policy/hs/hs_policies.htm

Human Subjects Protections Training: <http://grants.nih.gov/grants/policy/hs/training.htm>

Application Guide SF424 (R&R) (for electronic submissions):

http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerB.doc.

Do I need to include a data safety monitoring plan in my application if my project is a clinical trial?

Yes. All clinical trials supported by NINR require some form of monitoring based on a data and safety monitoring (DSM) plan. The level of monitoring should be commensurate with the size and complexity of the trial, the level of risk to study participants, and phase of the trial. All mechanisms for data and safety monitoring are subject to IRB review and approval.

Responsibility for data and safety monitoring may be conducted by the Principal Investigator or designee. Monitoring by the Principal Investigator or designee may be appropriate for protocols involving no more than a minor increase over minimal risk which are conducted at a single site. Data and safety monitoring may also be conducted by independent entities external to the study team such as an independent safety monitor (ISM), small committees (safety monitoring committee; SMC) or Data and Safety Monitoring Boards (DSMBs).

A DSMB is generally required for *phase III clinical trials*. The organization, responsibilities, and operation of the DSMB are mandated by NIH and NINR policy. Exceptions to oversight using a DSMB will be considered for Phase III clinical trials if it can be established that the intervention poses no more than minimal risk, as defined by 45 CFR Subpart A, Sec. 46.102 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>) and minimal risk to data integrity and quality (for example—small number of sites, small sample size, few data elements, short duration). A DSMB may be required for *Phase I or phase II* clinical trials that have multiple sites, or are blinded, or include high-risk interventions, high risk procedures (particularly invasive or is associated with other safety concerns), or vulnerable populations (children, pregnant women, elderly, terminally ill, or those of diminished mental capacity).

What are the requirements for including women and minority subjects in NIH-funded studies?

NIH policy requires the inclusion of women and members of minority groups and their subpopulations in all NIH-supported biomedical and behavioral research projects involving human subjects unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant institute or center director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an institute or center director based on a compelling rationale and justification. The award will require that for each funded protocol, investigators must report in their annual Progress Report cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences. Inclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions. This policy applies to research subjects of all ages. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. NIH funding components will not award any grant, cooperative agreement, or contract or support any intramural project that does not comply with this policy.

The grant application instructions contain information that must be submitted. Specific factors to be considered in making determinations about the inclusion of women and minorities in clinical trials are described in the amendment to NIH Guidelines on the Inclusion of Women and Minorities as Other resources include and overview page and a list of additional policy implementation resources:

http://grants.nih.gov/grants/funding/women_min/women_min.htm

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Submission and Review Process

An excellent set of resources about the entire review process is available in two short videotapes and in documents for online review or downloading.

**NIH Peer Review Revealed
NIH Tips for Applicants**

When should I submit my application?

NIH follows an established receipt, review, and award schedule. Special receipt dates may be specified in program announcements, requests for applications, and program guidelines. You can obtain a list of upcoming receipt dates [here](#). Note that AIDS-related applications have different submission schedules; therefore, it is important to check the heading for the mechanisms of interest.

See also the dates for transition to electronic submission for each set of mechanisms. Scroll below the submission schedule for policies regarding various submission topics.

Whom do I contact before the initial review of my application?

Call the scientific review officer of the scientific review group reviewing your application. For a CSR study section, go to the [CSR Study Section Roster Index](#); for an NINR review group, go to our Office of Review staff list (<http://www.ninr.nih.gov/ResearchAndFunding/DEA/OR/>)

How does the NIH Center for Scientific Review (CSR) make decisions about the assignment of applications to institutes and centers?

After your application arrives at NIH, it is examined by the NIH Center for Scientific Review (CSR) for completeness and relevance to the NIH mission. If the application is relevant and complete, CSR determines how it "fits" within the programs of the various institutes and centers, and an assignment is made to one or more institutes or centers for funding consideration. When your application is submitted in response to a request for applications (RFA), it is examined for relevance by the sponsoring institute or center.

Decisions about the primary assignment of applications in areas of overlapping research interests have been carefully negotiated among the NIH institutes and centers. When your application is assigned to two or more institutes or centers, the "primary" institute or center becomes your point of contact for following the progress of review and funding decisions. The "secondary" institutes or centers, which are potential alternative or collaborative sources of funding, also track the application.

To assist CSR in its assignments, you are permitted, and in some cases even encouraged, to send a cover letter with your application suggesting assignment to a specific institute or center and explaining how the research addresses its mission. NIH program staff members, if they know of your interest, can also notify CSR that they are "awaiting receipt of an application" (known as an ARA notice).

In the same cover letter, you may request assignment to a specific study section, which is also handled by CSR. CSR takes these suggestions very seriously. However, the final decisions regarding application referral and assignment are made by CSR.

How does NIH make decisions about the assignment of applications to study sections?

Upon receipt of an application, the NIH Center for Scientific Review (CSR) assigns it to the appropriate study section according to the scientific emphasis of the proposed research and guidelines that delineate the scientific expertise of each study section. Assignments are made by senior science administrators who have had research and scientific review administrator experience. Applicants may include a cover letter requesting assignment of their applications to specific study sections, as well as referral to specific institutes or centers, but final decisions regarding assignment and referral rest with CSR. Reviews of applications for certain funding mechanisms, such as

Individual Fellowships (F31s and F32s) and Institutional Research Training Grants (T32s), as well as responses to requests for applications (RFAs), are conducted by review committees convened by NINR or whichever institute or center to which the application has been assigned.

How does the NIH application review process work?

The NIH peer review system for grant applications is federally regulated — see [42 CFR Part 52h](#) and is based on two sequential levels of review, referred to as the "dual review system." The first level of review is conducted by panels of expert consultants established according to scientific disciplines, current research areas, or other appropriate expertise as needed. The primary purpose of a peer review panel is to evaluate the scientific and technical merit of grant applications. The second level of review is conducted by National Advisory Boards or Councils composed of both scientific and lay representatives. At NINR, this second level of review is performed by the National Advisory Council for Nursing Research (<http://www.ninr.nih.gov/AboutNINR/NACNR/>). For a detailed explanation of the NIH review process, see the NIH OER: Peer-Review Policies and Practices [Web page](#).

In addition, there is additional information on the [enhancing peer review system](#) (

<http://enhancing-peer-review.nih.gov/index.html>) as well as a video (http://enhancing-peer-review.nih.gov/application_changes_video.html).

How long will I have to wait for my summary statement?

You will receive a summary statement through the [eRA Commons](#) roughly six to eight weeks after the review meeting, or earlier for new investigators.

What criteria do members of scientific review groups use to evaluate grant applications?

Scientific review groups evaluate the scientific merit of each grant application according to specific criteria. For renewal and revision applications, reviewers must also consider progress to date. In the case of resubmitted applications, reviewers must evaluate applicants' revisions of earlier proposals made in response to previous reviews. See these recent changes in terms:

- “Competing Continuation” is now termed “Renewal”
- “Revision” or “Amendment” is now termed “Resubmission”
- “Competing Supplement” is now termed “Revision”

NIH uses five explicitly-stated review criteria, published in the NIH Guide Notice Dec. 2, 2008 (<http://grants.nih.gov/grants/guide/notice-files/not-od-09-025.html>) for all unsolicited research applications. Applications solicited through RFAs will use the review criteria in the announcement.

There are specific guidelines for NIH reviewers that are publicly available at:
http://grants.nih.gov/grants/peer/reviewer_guidelines.htm

Where can I get a list of all of the study sections that review applications submitted to NIH?

It is useful to review study section purposes and rosters to determine the best match for your application. The Center for Scientific Review attempts to honor applicant requests for assignment to a study section, however, CSR makes the final decision based on a number of factors.

What can I do if I do not agree with the review of my application?

The best approach is to avoid a flawed review due to conflicts by taking these pre-emptive steps:

- 1) Declare any known conflicts between any standing study section members or any expert/scientist with known difference of scientific opinion or personal conflict with you or any member of your research group. Put this into a cover letter accompanying your application in order to alert the Scientific Review Officer of this potential conflict of interest.
- 2) View the review group membership upon receiving your study section assignment and when the actual roster membership is available for viewing, (usually published 30 days in advance of the review meeting). If there are potentially conflicted members on the panel that should not review your application, alert the Scientific Review Official of the potential conflict(s).

NIH has an established appeals process for applicants who think that some aspect of the handling or initial review of their grant applications has been inappropriate. Applicants may dispute the results of an initial peer review based on an error in the review process, such as reviewer bias, factual error, or reviewer conflict of interest, but not a difference of scientific opinion.

Applicants who have concerns about the review of their submission should first discuss the issues with the Institute program director assigned to the project. The issues of concern are almost always differences of scientific opinion and the investigator's time may be more productively spent in revising and resubmitting the application.

Program Directors, either alone or with Scientific Review Administrators (SRAs), usually resolve issues with applicants. The Institute's Advisory Council reviews cases that cannot be resolved, but rarely overturns initial peer review results. In most cases, Council recommends that applicants revise and resubmit their application. The appeals process is triggered when an applicant submits a letter detailing specific concerns about the review of the application to the institute/center program

director. Detailed information regarding this process, including grounds for review, can be found in the Grants Policy Statement at:

http://grants.nih.gov/grants/policy/nihgps_2001/part_iiia_7.htm#GrantAppealsProcedures

It should be noted that differences of scientific opinion that may occur between investigators and reviewers may not be contested through these procedures. In addition, communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals. Finally, appeals of receipt and referral issues regarding applications not yet reviewed should be directed to the Referral Office in the Center for Scientific Review.

What are my chances of being funded by the National Institute of Nursing Research?

NINR funds about one out of four or five R01 applications it receives, an average comparable to that for the rest of NIH. In preparing an application for submission to any of the NIH institutes or centers, your primary challenge is to stimulate the enthusiasm of the study section that evaluates the scientific merit of the proposal. Competition for research funding is intense, and it is not unusual for an application not to be funded on its first submission. As with most creative endeavors, biomedical research requires not only good ideas but also perseverance. An application that is not submitted, however, will have zero chance of funding.

What should I do if my application is not funded?

On April 15, 2010, NIH issued a clarification on the resubmission policy, NOT-OD-080.

Applications are allowed only one resubmission (A1). The resubmission policy applies to all types of applications, every activity code, and applications submitted in response to Program Announcements (PA, PAR, PAS) or Requests for Applications (RFA).

If your application is not funded, you should carefully consider the reviewers' suggestions contained in the summary statement. You are encouraged to make a phone appointment to discuss the review concerns with your Program Director. You may then want to revise the proposal accordingly and resubmit it. However, you should use your own best scientific judgment in respectfully addressing the review concerns. Directions for preparing resubmitted applications are contained in the application instructions.

A new application following a total of two reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a resubmitted application. Simply rewording the title and Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction

and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections. The following link provides additional details about the requirements for a new application: <http://cms.csr.nih.gov/ResourcesforApplicants/OverlapEvaluation.htm>.

Funded Investigators

What is the meaning of the term Just-in-time and how does it relate to my application?

See the NIH grants [policy statement](#) about the pre-award process and just-in-time requirements. NIH uses just-in-time procedures for certain programs and award mechanisms. These procedures call for limited information (e.g., a budget justification and a biographical sketch) to be submitted with investigator-initiated applications and allow for a possible NIH request for additional information, including information concerning other support, when the application is under consideration for funding. Just-in-time procedures also allow an applicant to defer certification of IRB approval of the project's proposed use of human subjects, verification of IACUC approval of the project's proposed use of live vertebrate animals, and evidence of compliance with the education in the protection of human research participants requirement until after completion of the peer review and just prior to funding. Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions. Please note that receiving a request for JIT is not an indication of imminent funding, only CONSIDERATION of funding.

What is a NGA?

A copy of the 'Notice of Grant Award' (NGA) will appear in your NIH commons profile after your institution has been issued the actual grant award. Read this document very carefully as it contains important information regarding any restrictions on personnel or on amounts of money. Additionally, it outlines mandated reporting, certification and/or registration requirements. In the last funding year of your project, your final NGA will have detailed instructions for your final progress report and close out instructions.

What is a competing continuation?

A competing continuation is now called a **renewal**. A renewal application extends a project period that would otherwise expire for one or more grant budget periods; these grant applications are peer reviewed in a regular review cycle and compete with others for funds. A renewal is a continuation of the original study but adds significantly to the science by extension and advancement of the original aims. New populations can be added, along with additional aims that extend the study but not to

replace the original aims.

What should I do when my grant ends?

There are two websites that have essential information about grant management, including grant closure. The first site contains questions and answers about grant management and includes NIH websites related to grants policies:

<http://www.ninr.nih.gov/ResearchAndFunding/GrantDevelopmentandManagementResources/ManagingninrfundedgrantsFile.htm>

The second site is an NIH Grants Policy site that includes discussion of grant closure issues and other potential activities occurring at the end of a grant.

http://grants.nih.gov/grants/policy/nihgps/part_ii_7.htm#closeout

Finally, your last NGA will include links and instructions to help complete the close-out process.